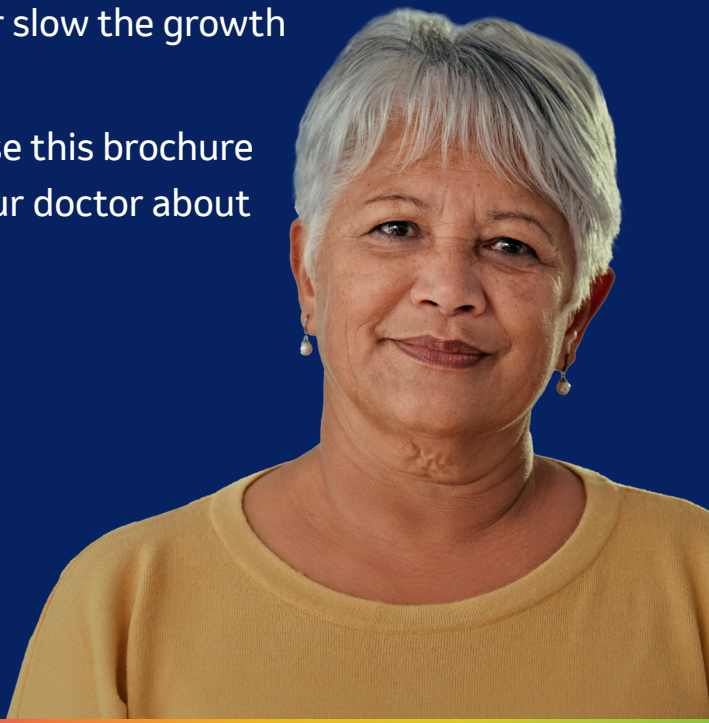
TroFuse 011
ONCOLOGY CLINICAL TRIALS

Learn about a clinical trial for **Triple Negative Breast Cancer**

In this brochure, you will learn about **triple negative breast cancer (TNBC)** and a clinical trial for this disease. In this trial, researchers are trying to learn if a new investigational drug, called sac-TMT, by itself or in combination with another investigational drug, pembrolizumab, may help work to stop or slow the growth of cancer cells.

You can also use this brochure to talk with your doctor about this trial.



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What is Triple Negative Breast Cancer?

Triple negative breast cancer (TNBC) is a type of breast cancer that grows faster and more aggressively than other types.

All breast cancer cells can:

- Have 2 types of proteins on their surface (called receptors):
  - Estrogen receptors (ER)
  - Progesterone receptors (PR)
- Make a protein called HER2

"Triple-negative" means the breast cancer cells do not have estrogen or progesterone receptors (ER or PR) and do not make any or a little amount of HER2. It is called "negative" because the cells test negative for these 3 features.

What are my treatment options?

If you have TNBC, your care team will talk about your treatment options with you and those close to you. Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms
- Features of your cancer cells (called biomarkers) that may help guide your treatment

Your care team may offer you 1 or more of these treatments:

- **Targeted therapy** – treatment that works on specific cells to stop them from growing
- **Immunotherapy** – medicines that help your immune system fight the cancer
- **Chemotherapy** – medicine to kill cancer cells or stop them from growing
- **Radiation therapy** – reatment that uses beams of intense energy (like X-rays) to shrink or get rid of cancer cells.
- **Palliative care** – also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat TNBC but it helps keep you as comfortable as possible.
- **Surgery** – treatment to remove all or part of the cancer
- **Clinical trials**, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

The goal of this trial is to learn if a new investigational drug, called sacituzumab-tirumotecan (abbreviated sac-TMT and also known as MK2870), by itself or in combination with another investigational drug, pembrolizumab, may help work to stop or slow the growth of cancer cells. Researchers don't know if sac-TMT or the combination of sac-TMT plus pembrolizumab may help to treat TNBC. Sac-TMT and the investigational combination are experimental and have not been approved for use.

What treatment is being studied?

There are two study drugs, one is called sac-TMT and the other is called pembrolizumab.

Researchers will compare:

- The investigational drug sac-TMT by itself
- The investigational combination of sac-TMT plus pembrolizumab
- Physician's choice of chemotherapy

About Sacituzumab-tirumotecan

Sac-TMT (MK-2870) is a type of investigational targeted therapy known as an antibody drug conjugate (ADC) that may destroy cancer cells.

A targeted therapy is a treatment that works on specific cells, tissues, or organs to stop them from growing. Unlike traditional chemotherapy, ADCs have 3 parts:

- **A monoclonal antibody:** A protein that binds to specific proteins or receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is TROP2.
- **An anti-cancer drug:** A type of drug that is meant to kill cancer cells
- **Linker:** Connects the anti-cancer drug to the monoclonal antibody

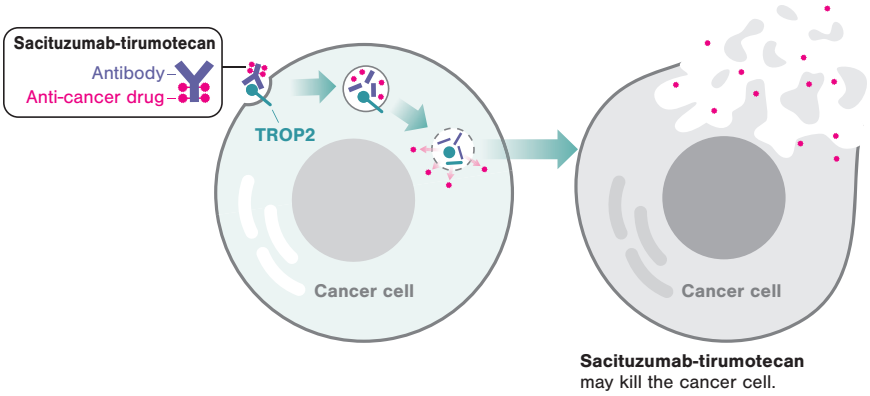
How Researchers Think sac-TMT May Work:

1. TROP2 receptors are involved in how tissues in the body grow. These are more common in cancer cells.
2. The monoclonal antibody in sac-TMT finds and binds to the TROP2 receptors on cancer cells.
3. TROP2 moves sac-TMT into the cancer cell where the anti-cancer drug is released.
4. Once inside the cancer cell, the anti-cancer drug may kill the cancer cell.

This is what scientists know or assume about how the investigational drug may work.

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

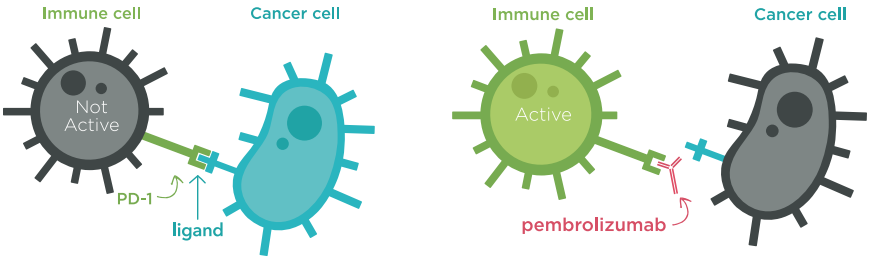
Another way to think about sac-TMT



About pembrolizumab

1. A protein called PD-1 (on some of your immune system cells) sometimes binds with certain molecules called ligands (on some cancer cells)
2. When these 2 bind, it turns off the immune system cell, which means it can't do its work to help protect you and attack cancer cells
3. This is where pembrolizumab comes in - this study drug binds with PD-1 and blocks PD-1 from binding with ligands
4. By blocking PD-1 from binding with ligands, pembrolizumab may help the immune system find and attack cancer cells

Another way to think about pembrolizumab



When PD-1 and ligands bind, it's like turning off the immune cell. This means that the immune cell will not do its work to attack cancer cells.

Who can join this trial?

There are eligibility criteria that will determine if you will qualify for participation. For example, you must:

- Have TNBC that has spread to other parts of the body or can't be removed by surgery
- Have the tumor tested for 2 biomarkers called PD-L1 and TROP2
    - ➤ To qualify, the tumor must have any level of TROP2 and a CPS score <10 indicating a low level of PD-L1

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- The response of your cancer to the treatments
- How well you tolerate the study treatments

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the study drugs are working for you. During your trial visits, you may get:

- Eye Exams
- Your assigned study drug
- Blood and urine (pee) tests
- Physical exam
- Imaging scans that help the doctor see the cancer inside your body, such as MRI or CT scans
- Questions about how you are feeling, including any side effects you may have

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the study treatment works over time.

What treatments will I get?

The study drug you get will depend on which group you are randomly placed in. all groups will receive their study drug through a needle in their vein, called an IV (intravenous) infusion.

There are 3 groups:

- **Group 1** will get the investigational drug sac-TMT
- **Group 2** will get the investigational combination sac-TMT and pembrolizumab
- **Group 3** will get their doctor's choice of chemotherapy (either paclitaxel or nab-paclitaxel or carboplatin plus gemcitabine)

A computer will decide which group you are put in. There is a 40% chance to be placed in group 1, a 20% chance to be placed in group 2, and a 40% chance to be placed in group 3.

You, your trial doctor, and the trial staff will know which treatments you are getting.

Thank you for learning about Triple Negative Breast Cancer and this clinical trial

You can use this brochure to talk with your doctor about this trial.

Your questions and notes:

You can use this space to write down notes or questions about this trial.

Notes:

Notes:

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Visit **www.merckoncologyclinicaltrials.com**
- Scan this QR code:

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